UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF WISCONSIN

INNOGENETICS, N.V.,
a Belgian Corporation,

Plaintiff,

v. **Case No. 05-C-0575-C**

ABBOTT LABORATORIES,
an Illinois Corporation,

Defendant.

PLAINTIFF'S PROPOSED FINDINGS OF FACT IN SUPPORT OF PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT OF NO INEQUITABLE CONDUCT

Plaintiff Innogenetics, N.V. ("Innogenetics") proposes the following facts in support of Plaintiff's Motion For Summary Judgment Of No Inequitable Conduct.

I. JURISDICTION AND VENUE

1. This Court has subject matter jurisdiction based on 28 U.S.C. §§ 1331 and 1338(a), in that this action arises under the patent laws of the United States (35 U.S.C. §§ 1, *et seq.*). Answer ¶ 3 (dkt. 007).

2. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b) and (c) and 1400(b). Answer ¶ 3 (dkt. 007).

II. THE PARTIES

3. Plaintiff Innogenetics is a Belgian corporation having its principal place of business at Technologie Park 6, 9052 Ghent, Belgium. Answer ¶ 1 (dkt. 007).

4. Defendant Abbott Laboratories ("Abbott") is an Illinois corporation with its principal place of business at 100 Abbott Park Road, Abbott Park, Illinois, 60064-6400. Answer ¶ 2 (dkt. 007).

III. BACKGROUND

A. Filing of U.S. Patent Application No. 08/256,568 on July 18, 1994.

5. On July 18, 1994, Maertens *et al.*, filed U.S. Patent Application, Serial No. 08/256,568 ("the '568 application"), entitled "Process for Typing HCV Isolates," in the United States Patent and Trademark Office ("USPTO") pursuant to 35 U.S.C. § 371. Glazer Decl. Ex. 1, excerpts from the certified prosecution history of U.S. Patent No. 5,846,704 ("the '704 patent"), at 00162-164.

6. The '568 application listed four inventors, Dr. Geert Maertens, Dr. Lieven Stuyver, Dr. Rudi Rossau and Dr. Hugo van Heuverswyn ("Applicants" or "Maertens *et al.*"). Glazer Decl. Ex. 1 at 00004.

7. The '568 application disclosed a method of genotyping isolates of the hepatitis C virus ("HCV") using probes that targeted sequences from the 5' untranslated region ("5' UTR") of HCV. Glazer Decl. Ex. 1 at 00005.

8. As filed, the '568 application contained 23 claims. Glazer Decl. Ex. 1 at 00004.

9. Charles Muserlian, a United States patent attorney, prosecuted the '568 application before the USPTO on behalf of Maertens *et al.* Glazer Decl. Ex. 1 at 00157.

10. The '568 application was the U.S. national stage of international Patent Cooperation Treaty ("PCT") application PCT/EP93/03325 ("Maertens PCT application"), which was filed on November 26, 1993. Glazer Decl. Ex. 1 at 00083.

11. The Maertens PCT application was published as WO 94/12670 on June 9, 1994. Glazer Decl. Ex. 1 at 00322.

12. The Maertens PCT application claims priority to European Patent Office ("EPO") Application No. 93402129.6, filed on August 31, 1993, and EPO 92403222.0, filed on November 27, 1992. Glazer Decl. Ex. 1 at 00083.

13. On July 18, 1994, Mr. Muserlian also filed, *inter alia*, the International Search Report, also referred to as Form PCT/ISA/210 ("ISR"), copies of the eight references cited in the ISR, a Prior Art Statement, the European Search Report, and PTO Form 1449. Glazer Decl. Ex. 1 at 00151-155; 00157-161.

14. The International Searching Authority issued the ISR on June 2, 1994. Glazer Decl. Ex. 1 at 00323.

15. The USPTO acknowledged receipt of the papers described at PPFF 13 on July 18, 1994. Glazer Decl. Ex. 2, Muserlian prosecution file, at Muserlian 000254-255.

16. One of the cited references in the ISR was PCT Application WO 92/19743, filed by Cha *et al.* on May 8, 1992, entitled "HCV Genomic Sequences for Diagnostics and Therapeutics," and published on November 12, 1992 ("the Cha PCT application"). Glazer Decl. Ex. 1 at 00323; 00326.

17. The ISR designated the Cha PCT application both as an "X" document ("the claimed invention cannot be considered novel or cannot be considered to involve an inventive step") and as an "A" document ("document defining the general state of the art which is not considered to be of particular relevance"). Glazer Decl. Ex. 1 at 00323.

18. The Cha PCT application was the only reference noted on the ISR as being an "X" document. Glazer Decl. Ex. 1 at 00323-324.

19. The X designation on the ISR emphasizes to the examiner the need for review and consideration of the document and, as a matter of patent office practice, the U.S. examiner will review and consider such a document. Expert Report of Michael Sofocleous ("Sofocleous Rpt.") ¶ 144 (dkt. 043).

20. As a matter of patent office practice, an examiner will review and consider an " X" document. Sofocleous Rpt. ¶ 144 (dkt. 043).

21. Seven other prior art references were also noted on the ISR as being "A" documents. Glazer Decl. Ex. 1 at 00323-324.

22. Two copies of the Cha PCT application can be found in the certified copy of the '568 application's prosecution history. Glazer Decl. Ex. 1 at 00326-511; 01188-1384.

23. The first page of the first copy of the Cha PCT application that appears in the certified prosecution history bears a date stamp of "18 JUL 1994". Glazer Decl. Ex. 1 at 00326.

24. Page 1 of the ISR described at PPFF 13 contains a written check mark, next to "WO, 92, A, 19743." Glazer Decl. Ex. 1 at 00323.

25. This check mark denotes at a minimum receipt by the PTO and suggests review by the examiner. Sofocleous Rpt. ¶ 66 (dkt. 043).

26. The Prior Art Statement submitted by Mr. Muserlian on July 18, 1994, read as follows:

> In order to comply with the requirements of Rule 56, Applicants are submitting herewith copies of the references cited in the search report in the French application corresponding to the above

> application as well as PTO form 1449. A copy of the search report was submitted with the application as filed. It is deemed that the references do not relate to the invention and, therefore, further discussion of the same is not necessary.

Glazer Decl. Ex. 1 at 00157.

27. Ten days after the filing described in PPFF 5, on July 28, 1994, Applicants filed a "Note Transmittal," informing the USPTO that the original Prior Art Statement incorrectly stated that the search report came from the French application in error and explained that the search report actually came from the European application. Glazer Decl. Ex. 1 at 00519.

28. Applicants stated as follows in the Note Transmittal:

> In reviewing the above application, it was noted that the Search Report being submitted with the application issued in the French patent corresponding to the application as can be easily seen from the documents submitted with the Prior Art Statement it was a Search Report issued in the corresponding European Application. The error is regretted.

Glazer Decl. Ex. 1 at 00519.

29. The Note Transmittal also included copies of the PTO Form 1449 and Prior Art Statement originally filed on July 18, 1994. Glazer Decl. Ex. 1 at 00519.

30. The USPTO acknowledged receipt of the papers described at PPFF 26 and 29. Glazer Decl. Ex. 2 at Muserlian 000216-000217.

31. On October 19, 1994, Rita D. Smoot, a Legal Document Review Clerk, reviewed the filed documents, indicating, *inter alia*, receipt of PCT/ISA/210-Search Report and the references cited therein. Glazer Decl. Ex. 1 at 00844.

32. Ms. Smoot noted that on July 18, 1994, the requirements of 35 U.S.C. § 371 were met. Glazer Decl. Ex. 1 at 00844.

33. On October 21, 1994, the USPTO mailed a Notification of Acceptance of Application under 35 U.S.C. § 371. Glazer Decl. Ex. 1 at 00520.

34. The Notification acknowledged receipt, *inter alia*, of the following documents: the Preliminary Amendment, filed July 18, 1994; Information Disclosure Statement, filed July 18, 1994; a copy of the search report and copies of the references cited therein. Glazer Decl. Ex. 1 at 00520.

B. The Prosecution of the '568 Application.

35. Examiner Amy Atzel, Ph.D., was the assistant examiner for the '568 application. Glazer Decl. Ex. 3, U.S. Patent No. 5,846,704 ("the '704 patent") at 1.

36. Examiner W. Gary Jones supervised Examiner Atzel's work on the '568 application as a supervisory patent examiner ("SPE"). Sofocleous Rpt. ¶ 108 (dkt. 043).

37. Examiner Atzel conducted her own search of the prior art. Glazer Decl. Ex. 1 at 01615.

38. Examiner Atzel attached the results of her search to a PTO Form-892, which is a Notice of References Cited. Glazer Decl. Ex. 1 at 00747.

39. In 1992 Cha *et al.* published an article in the journal Proceedings of the National Academy of Sciences entitled "At least five related, but distinct, hepatitis C viral genotypes exist" ("the 1992 Cha article"). Glazer Decl. Ex. 4, the 1992 Cha article at 7144.

40. The PTO Form-892 lists, *inter alia*, the 1992 Cha article. Glazer Decl. Ex. 1 at 00747.

41. The 1992 Cha article was communicated to the journal nine days before the Cha PCT application was filed. Glazer Decl. Ex. 4 at 7144; *see* PPFF 16, *supra*; Second Expert Report of Howard J. Worman at 14 (dkt. 041).

42. The Cha PCT application named five inventors, each of whom are among the six authors of the 1992 Cha article. Glazer Decl. Ex. 1 at 00326; Glazer Decl. Ex. 4 at 7144.

43. In the 1992 Cha article, Cha *et al.* concluded as follows:

> * * * It is imperative to examine longer segments of sequence for each isolate in several domains to discern different genotypes. For instance, isolates US4 and US5 cannot be assigned to different genotypes based on the 5UT region alone (Fig. 2A) unless other domains (Fig. 2B and C) are taken into consideration.
>
> ...
>
> When only the 5UT region is considered, fewer distinct genotypes can be assigned. On the other hand, when only the hypervariable region is considered, each isolate will represent a unique genotype. We should emphasize that long segments of sequence in several

> domains should be examined together for each isolate to classify its genotype.

Glazer Decl. Ex. 4 at 7146; 7148 (emphasis added).

44. A Preliminary Amendment to the '568 application was submitted on July 18, 1994. Glazer Decl. Ex. 1 at 00516-518.

45. The purpose of the Preliminary Amendment was to conform the claims set forth in the Maertens PCT application with USPTO procedures. Glazer Decl. Ex. 1 at 00518.

46. On April 8, 1996, examiner Atzel issued an Office Action in which she stated that the claims are directed to three patentably distinct inventions, *i.e.*, Group I (Claims 1-5 and 8-18) drawn to processes for genotyping HCV, Group II (Claims 6 and 7) drawn to DNA or RNA probes, and Group III (Claims 19-23) drawn to a kit and solid supports for *in vitro* discrimination of HCV isolates. Glazer Decl. Ex. 1 at 00729-731.

47. Examiner Atzel required the prosecution of the '568 application to be restricted to one of Groups I-III. Glazer Decl. Ex. 1 at 00730.

48. On May 2, 1996, Maertens *et al.* filed a Response to the Office Action informing the examiner that they elected the claims of Group I. Glazer Decl. Ex. 1 at 00739-740.

49. On July 12, 1996, examiner Atzel mailed a Second Office Action. Glazer Decl. Ex. 1 at 00741-746.

50. In the Second Office Action, examiner Atzel acknowledged, *inter alia*, the election of Group I. Glazer Decl. Ex. 1 at 00742.

51. Examiner Atzel then continued in the Second Office Action to set forth her reasons for rejecting the claims of Group I, *inter alia*, as obvious pursuant to 35 U.S.C. § 103 over several prior art references. Glazer Decl. Ex. 1 at 00745.

52. Three of these references relied on by examiner Atzel in the Second Office Action – Bukh *et al.*, Okamoto *et al.* (J. Gen. Virol.) and Lee *et al.* – were among those cited in the ISR that was submitted by Mr. Muserlian with the '568 application. Glazer Decl. Ex. 1 at 00745; *see* PPFF 15, *supra*.

53. Examiner Atzel also cited in her rejection the 1992 Cha article, as well as a November 1991 Cha article, J. Clin. Microbiol. 29:2528-34 (the "1991 Cha article"). Glazer Decl. Ex. 1 at 00744-745; 00747.

54. On January 13, 1997, Maertens *et al.* filed an Amendment in response to the Second Office Action. Glazer Decl. Ex. 1 at 00749-779.

55. In the Amendment, Maertens *et al.*, *inter alia*, canceled all the pending claims and added new claims 24 to 39. Glazer Decl. Ex. 1 at 00749-763.

56. In response to the examiner's rejections under 35 U.S.C. §§ 102 and 103, the Applicants made several arguments explaining why the invention claimed in the '568 application was unique and distinguishable over the prior art. Glazer Decl. Ex. 1 at 00764-774.

57. On April 18, 1997, examiner Atzel mailed the Final Office Action to the Applicants. Glazer Decl. Ex. 1 at 00780-786.

58. Examiner Atzel updated her search of the prior art prior to mailing the Final Office Action. Glazer Decl. Ex. 1 at 01615.

59. In the Final Office Action, examiner Atzel rejected the pending claims as unpatentable under 35 U.S.C. §§ 102 and 103 over several prior art references, including the 1991 and 1992 Cha articles. Glazer Decl. Ex. 1 at 00783-786.

60. At page 3 of the action, examiner Atzel stated:

> * * * The method of claim 24 is sufficiently broad that it reads on any method involving a "probe" or "primer" that is capable of hybridizing to the 5' UTR. Claim 24 is not limited to *probes that specifically hybridize* to the positions –291 to –66 of the 5'-UTR, but only to *probes capable of doing so* ....

Glazer Decl. Ex. 1 at 00783 (emphasis added).

61. The Final Office Action was reviewed and signed by examiner Atzel's supervisor, W. Gary Jones. Glazer Decl. Ex. 1 at 00786.

62. On October 2, 1997, Dr. Maertens, Mr. Muserlian and Dr. Philippe Jacobs, a representative from Innogenetics' patent department, attended an interview with examiner Atzel to discuss the '568 application. Glazer Decl. Ex. 1 at 00798; 00808.

63. During this interview, all pending claims as well as the "Cha" and "Okamoto" references were discussed. Glazer Decl. Ex. 1 at 00798.

64. The summary describes the general nature of what was discussed at the interview as follows:

> [Applicant] explained that using UTR for genoytyping is not motivated by prior art because UTR is highly conserved. Art says best probes are in "coding regions". UTR probes have been used for "detecting HCV" in general but not "typing". Discussed extensive revisions to claims that more clearly define invention.

Glazer Decl. Ex. 1 at 00798.

65. On October 20, 1997, Applicants filed a Rule 116 Amendment in response to the Final Office Action. Glazer Decl. Ex. 1 at 00799-00811.

66. In the Rule 116 Amendment, Applicants canceled claims 24-39 and added claims 40-52. Glazer Decl. Ex. 1 at 00799-00807.

67. Applicants also submitted Remarks to the examiner's reasons for rejection set forth in the Final Office Action dated April 18, 1997. Glazer Decl. Ex. 1 at 00808-811.

68. In response to the final rejection Applicants amended the claims to replace the phrase using a probe "capable of hybridizing" with the phrase "using a probe that specifically hybridizes." Glazer Decl. Ex. 1 at 00799; 00809.

69. On November 12, 1997, examiner Atzel mailed a Notice of Allowability and an Examiner's Amendment to the Applicants. Glazer Decl. Ex. 1 at 00820-00824.

70. By November 12, 1997, examiner Atzel had updated her prior art search and had conducted an interference search. Glazer Decl. Ex. 1 at 01615.

71. The Notice of Allowability stated the reasons for allowing the claims over the prior art as follows:

> The examiner's amendment above obviates outstanding rejections to claims under 35 USC 112 second paragraph remaining in the response after final of 10-21-97 per interview of 10-2-97. The examiner's amendment rectifies questions of clarity and distinctness only and does not limit scope of claims. The nucleotide numbering used in the specification and claims is understood to be standard in the art, wherein nucleotide 1 is the first base of the initial ATG codon and -1 is the base immediately 5' to the initial A. *The claims are allowable over the prior art because the instant methods are concerned with "genotyping" HCV rather than just "detecting" HCV.* Although genotyping falls under the umbrella of detecting, it is a specific and selective type of detection whereby different genotypes of similar virus strains can be distinguished. Mere

> detection methods permit detection of numerous types and subtypes of HCV without distinguishing among them. Hence, the term "method of genotyping" means distinguishing among HCV types and/or subtypes. The prior art recognizes the problem of genotyping HCV versus detecting HCV and others have developed methods of genotyping by exploiting sequences that are non-conserved among HCV types. The most divergent sequences have turned out to be in coding regions of the HCV genome. Okamoto et al. (1992) J. Gen. Virol. use the "C" gene as [the] basis for distinguishing genotypes. *The instant inventors have gone against conventional wisdom and used the 5'-untranslated region to make probes for genotyping. The 5'-UTR has not been used before for genotyping because it is so highly conserved among isolates.* Applicant, however, has found specific regions, that apparently belong to a stem loop structure, in the 5'-UTR that exhibit enough heterogeneity among isolates to be exploited for genotyping. *Although the sequences of several HCV 5'-UTR are known in the art, and genotyping methods are known in the art, it is not suggested or motivated to use the 5'-UTR for genotyping. Indeed, the ordinary artisan would be motivated to avoid the 5'-UTR for genotyping because of its high sequence conservation.* Moreover, Cha et al. (1991) use the 5'-UTR to design "universal probes" for general HCV detection just because the 5'-UTR is so highly conserved.

Glazer Decl. Ex. 1 at 00821 (emphasis added).

72. The Notice of Allowability was drafted by examiner Atzel and was reviewed and signed by her supervisor, W. Gary Jones. Glazer Decl. Ex. 1 at 00822.

73. On December 8, 1998, the '568 application issued as U.S. Patent No. 5,846,704 ("the '704 patent"), disclosing a rapid method of genotyping in which oligonucleotide probes are specifically hybridized to target regions in the 5' UTR of HCV. Glazer Decl. Ex. 3 at 1; col. 2, ll. 39-44; col. 113, ll. 1-7.

74. The '704 patent is assigned to Innogenetics, N.V. Glazer Decl. Ex. 3 at 1.

IV. Abbott's Contentions of Inequitable Conduct

75. Abbott brought two incomplete copies of the prosecution history of the '704 patent to Mr. Muserlian's deposition on January 11, 2006. Glazer Decl. Ex. 7, Muserlian Dep. Tr. at 93-94.

76. Both incomplete copies contained a copy of the Cha PCT application bearing the date stamp "18 JUL 1994." Glazer Decl. Ex. 8, excerpts from Muserlian Dep. Exs. 5 & 6 (TWT 004122, TWT 008601).

A. Abbott's Expert on European Patent Law

77. Devanand John Crease, a European patent attorney, was retained by Abbott's counsel to opine on the prosecution history of European Patent No. 0637342, the European counterpart to the '704 patent. Glazer Decl. Ex. 6, Crease Dep. Tr. at 15.

78. When there are simultaneous prosecutions related to the same invention in Europe and the United States, the standard practice is to simply supply the USPTO with any international search reports and the references cited therein. Glazer Decl. Ex. 6 at 171-173.

79. The prosecuting attorney's obligation during prosecution in the USPTO is to "disclose all prior art documents that are either relevant in your mind or that are raised during prosecution in Europe or elsewhere in the world, in the U.S." Glazer Decl. Ex. 6 at 66.

B. Muserlian's Prior Art Statement

80. It was Mr. Muserlian's normal practice to file a Prior Art Statement with a patent application in the USPTO. Glazer Decl. Ex. 7 at 110.

81. The text quoted at PPFF 26, *supra*, ("It is deemed that the references do not relate to the invention and, therefore, further discussion of the same is not necessary") was Mr. Muserlian's standard form language he used in such circumstances. Glazer Decl. Ex. 7 at 110-111 ("I just say here's the prior art and it doesn't look to be relevant and, you know, if the examiner deems it relevant he cites it and then we discuss it from there.").

82. Ann De Clercq, a member of Innogenetics' patent department at the time of the prosecution of the '568 application, expressly agreed with the contents of the Prior Art Statement. Glazer Decl. Ex. 9, De Clercq Dep. Tr. at 28-29; 113-114

83. The Prior Art Statement was also consistent with the Applicants' view that the Cha PCT application was not related to the invention disclosed in the '704 patent. Glazer Decl. Ex. 10, Maertens Dep. Tr. at 325-326.

C. European Prosecution of the Maertens PCT Application

84. On November 26, 1993, Maertens *et al.* filed European application no. 94901891.5 ("the EP '342 application") in the EPO. Glazer Decl. Ex. 11, European Patent No. EP 0637342 at 1.

85. The EP '342 application was published as Maertens PCT application on June 9, 1994. Glazer Decl. Ex. 11 at 1.

86. EP '342 application was granted as European patent no. 0637342 ("EP 342 patent"). Glazer Decl. Ex. 11 at 1.

87. The grant and date of publication of the EP '342 patent was April 28, 1999. Glazer Decl. Ex. 11 at 1.

88. The EP '342 patent is based on the Maertens PCT application. Glazer Decl. Ex. 11 at 1.

89. Claim 1 of the European patent claims "[u]se of at least one probe . . .", a use claim which does not have a corresponding claim in the '704 patent. Sofocleous Rpt. ¶ 188 (dkt. 043).

90. Claim 2 of the European patent recites a "[p]rocess for genotyping . . ." employing at least one probe "capable of hybridizing to a genotype specific target region . . .", which claim language is not present in the '704 patent. Sofocleous Rpt. ¶ 188 (dkt. 043).

91. The claim language quoted in PPFF 90 was specifically rejected by the U.S. examiner in view of the Cha *et al.* 1991 publication and the Okamoto *et al.* U.S. Patent No. 5,550,016. Sofocleous Rpt. ¶ 188 (dkt. 043).

92. In response to the Final Office Action dated April 18, 1997, Maertens *et al.* narrowed their claims to recite only methods of genotyping HCV in which probes specifically hybridize to the 5' UTR. Sofocleous Rpt. ¶ 188 (dkt. 043).

93. The scope of the European claims is both different and broader than the scope of the U.S. claims. Sofocleous Rpt. ¶ 188 (dkt. 043).

94. During prosecution of the European counterpart to the '704 patent, Maertens et al. took advantage of a procedural mechanism called a "disclaimer" which is not available in the United States. Sofocleous Rpt. ¶ 189 (dkt. 043).

95. Claim 2 of the EP 342 patent contains the disclaimer:

> with said process being different from an HCV genotyping process in which ^{32}P labeled sequences having the sequence AACCCACTCTATGYCCGGYCAT and GAATCGCTGGGGTGACCG, wherein Y means C or T/U, are used in a hybridization experiment with an immobilized PCR product generated using as primers the following sequences: CCATGAATCACTCCCCTGTGAGGAACTA and TTGCGGGGGCACGCCCAA.

Glazer Decl. Ex. 11, EP '342 patent at claim 2.

96. The EP '342 application was prosecuted under a "problem solution" framework common in European practice in which a piece of art – whether relevant or not – is termed the "closest prior art." Glazer Decl. Ex. 9 at 106-109.

97. Mr. Crease agreed with Ms. De Clercq's definition of "closest prior art." Glazer Decl. Ex. 6 at 44-45.

98. The laws and rules governing European patents and European patent practice are different from those governing U.S. patent practice. Sofocleous Rpt. ¶ 185 (dkt. 043).

99. The EPO received a copy of the same ISR that was received by the USPTO, listing the Cha PCT application as an "X" document. Glazer Decl. Ex. 12, ISR from European prosecution history of EP '342; Glazer Decl. Ex. 1 at 00323-325.

C. Simultaneous prosecution of the Maertens '704 patent and the Cha '693 patent.

100. On May 16, 1995, Cha *et al.*, filed application Serial No. 08/441,971 ("the Cha '971 application"). Glazer Decl. Ex. 13, U.S. Patent No. 6,071,693 ("Cha '693 patent") at 1.

101. The Cha '971 application issued as the Cha '693 patent on June 6, 2000. Glazer Decl. Ex. 13, Cha '693 patent at 1.

102. The '971 application was a continuation of U.S. application Serial No. 07/881,528, filed May 8, 1992, which in turn was a continuation-in-part of U.S. application Serial No. 07/697,326 ("the '326 application"), filed May 8,1991. Glazer Decl. Ex. 13, Cha '694 patent at 1.

103. The Cha PCT application claims priority to the '326 application. Glazer Decl. Ex. 1 at 00326.

104. The Cha '971 application and the Cha PCT application both claim priority to U.S application Serial No. 07/697,326 ("the '326 application"). *See* PPFF 102, 103.

105. The specification of the Cha '971 application is identical to the specification of the Cha PCT application. Glazer Decl. Ex. 14, Declaration for Patent Application of the Cha '971 application.

106. As originally filed, the claims contained in the Cha '971 application were identical to the claims contained in the Cha PCT application. Glazer Decl. Ex. 1 at 00477-491; Glazer Decl. Ex. 15, '971 application at 150-164.

107. Ethan Whisenant was the assistant examiner responsible for the prosecution of the Cha '971 application. Glazer Decl. Ex. 13, Cha '693 patent at 1.

108. Examiner W. Gary Jones was the primary examiner responsible for the Cha '971 application, and he supervised examiner Whisenant's work on the Cha '971 application as an SPE. Glazer Decl. Ex. 13 at 1; Sofocleous Rpt. ¶ 116 (dkt. 043).

109. Examiner W. Gary Jones simultaneously oversaw the Maertens *et al.* '704 patent prosecution and the prosecution of the Cha '971 application, the U.S. counterpart to the Cha PCT application. Sofocleous Rpt. ¶¶ 114; 151-154 (dkt. 043); *see also* PPFF 104.

110. On December 12, 1995, the examiner of the Cha '971 application issued an Office Action, which was signed by his supervisor, SPE Jones. Glazer Decl. Ex. 16, office action issued during the prosecution of the Cha '693 patent, dated December 12, 1995, at 10.

111. The signature of an SPE indicates that the assistant examiner was neither a primary examiner nor an examiner having partial signatory authority because the work product of the assistant examiner must be reviewed by the SPE. Sofocleous Rpt. ¶ 151 (dkt. 043).

112. On September 20, 1996, the examiner of the Cha '971 application issued an Office Action, which was signed by his supervisor, SPE Jones. Glazer Decl. Ex. 17, office action issued during the prosecution of the Cha '693 patent, dated September 20, 1996, at 7.

113. On April 18, 1997, SPE Jones reviewed and signed the Final Office Action sent by examiner Atzel to Maertens *et al.* for the '568 application. Glazer Decl. Ex. 1 at 00786.

114. Six weeks later, on May 27, 1997, an Office Action sent to Cha *et al.* for the Cha '971 application was signed by SPE Jones in his supervisory capacity. Glazer

Decl. Ex. 18, office action issued during the prosecution of the Cha '693 patent, dated May 27, 1997, at 5.

115. On March 17, 1998, the examiner of the Cha '971 application issued a Final Office Action, which was signed by SPE Jones in his supervisory capacity. Glazer Decl. Ex. 19, office action issued during the prosecution of the Cha '693 patent, dated March 17, 1998, at 7.

116. As the supervisor in charge of the examination of both the Cha '971 application and the '568 application, it was the duty of SPE Jones to ensure that an interference would be declared if the claims of these two applications were directed to the same subject matter. Sofocleous Rpt. ¶ 162 (dkt. 043).

117. SPE Jones signed the Notice of Allowance for both the '568 application and the Cha '971 application. Glazer Decl. Ex. 1 at 00820-822; Glazer Decl. Ex. 20, notice of allowability issued during the prosecution of the Cha '693 patent.

118. SPE Jones allowed Cha *et al.*'s claims to a "method of detecting one or more genotypes of hepatitis C virus" comprising the steps of hybridizing nucleotide probes including probes in the 5' UTR of HCV nucleic acids. Glazer Decl. Ex. 13, Cha '693 patent at claims 20-28.

119. Methods of genotyping available prior to the '704 patent, including sequencing, were time-consuming and labor-intensive. Expert Report of Bruce K. Patterson, M.D. Regarding the Invalidity of Innogenetics, N.V.'s U.S. Patent No, 5,846,704 at 5 (dkt. 033); Expert Report of Howard J. Worman, M.D. at 5 (dkt. 037).

120. Abbott, in its answer to Interrogatory No. 1, has selected five phrases from eleven pages of remarks submitted in the Amendment of January 13, 1997. Glazer Decl. Ex. 1 at 00764-774.

121. Michael Sofocleous was formerly an employee of the USPTO for over 30 years, including 23 years as a patent interference examiner, Examiner-in-Chief and Administrative Patent Judge overseeing patent interferences. Sofocleous Rpt ¶¶ 7-18 (dkt. 043).

Dated this 15th day of May, 2006.

Attorneys for Innogenetics N.V.

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